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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/762,180	01/21/2004	Muthaiyyan Esakki Kannan	1276-37	4776

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EXAMINER

DICKINSON, PAUL W

ART UNIT	PAPER NUMBER
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1609

MAIL DATE	DELIVERY MODE
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09/05/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/762,180

Applicant(s)

KANNAN ET AL.

Examiner

Paul W. Dickinson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-145 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-145 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-144, drawn to a solid oral controlled release pharmaceutical composition, classified in class 424, subclass 468. *(Note: If Applicant elects Invention I, a further election is required below.)*
- II. Claim 145 drawn to a pharmaceutical composition which gives an improved method of extended release of the API from the dosage form, classified in class 424, subclass 468.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are directed to related products. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed have a materially different design. Specifically, Invention II does not require the same components as Invention I. Invention I is defined as requiring a controlled release modifying agent wherein said complex comprises (i) a primary release modifying agent and/or (ii) a secondary release modifying agent and (iii) an auxiliary release modifying agent. Invention II is not defined as requiring these

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components. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

- (a) the inventions have acquired a separate status in the art in view of their different classification;
- (b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;
- (c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);
- (d) the prior art applicable to one invention would not likely be applicable to another invention;
- (e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

In the instant case, the prior art applicable to Invention I would not likely be applicable to Invention II.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement

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may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected invention.**

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Election

If Applicant elects Invention I above, Applicant is further required under 35 U.S.C. 121 to elect a single disclosed species for each of the following six election requirements:

First Election Requirement of Six

This application contains claims directed to the following patentably distinct species: a pharmaceutically active ingredient (see Claims 6-28, 56-78, 101-123). Applicant is required to define the pharmaceutically active ingredient with a particular species (a species definition such as methyl, not a genus such as alkyl). The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claims 1-5, 29-55, 79-100, 124-144 are generic to the above.

Second Election Requirement of Six

This application contains claims directed to the following patentably distinct species: the presence or absence of a primary release modifying agent (see Claims 1-4, 55, 100). If Applicant elects the presence of a primary release modifying agent, Applicant is further required to define the primary release modifying agent with a particular species (a species definition such as methyl, not a genus such as alkyl). See

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Claims 29-31, 79-81. The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claims 5-28, 32-54, 56-78, 82-99, 101-144 are generic to the above.

Third Election Requirement of Six

This application contains claims directed to the following patentably distinct species: the presence or absence of a secondary release modifying agent (see Claims 1-4, 55, 100). If Applicant elects the presence of a secondary release modifying agent, Applicant is further required to define the secondary release modifying agent with a particular species (a species definition such as methyl, not a genus such as alkyl). See Claims 32-34, 124-126. The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claims 5-31, 35-54, 56-99, 101-123, 127-144 are generic.

Fourth Election Requirement of Six

This application contains claims directed to the following patentably distinct species: the presence or absence of an auxiliary release modifying agent (see Claims 1-4, 55, 100). If Applicant elects the presence of an auxiliary release modifying agent, Applicant is further required to define the auxiliary release modifying agent with a particular species (a species definition such as methyl, not a genus such as alkyl). See Claims 35-36, 82-83, 127-128. The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claims 5-34, 37-54, 56-81, 84-99, 101-126, 129-144 are generic to the above.

Fifth Election Requirement of Six

This application contains claims directed to the following patentably distinct species: the presence or absence of at least one pharmaceutical additive selected from diluents, fillers, binders, glidants, and lubricants (see Claims 37, 84, 129). If Applicant elects the presence of at least one pharmaceutical additive, Applicant is further required to define the pharmaceutical additive with a particular species (a definition species such as methyl, not a genus such as alkyl). The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of

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such species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claims 1-36, 38-83, 85-128, 130-144 are generic to the above.

Sixth Election Requirement of Six

This application contains claims directed to the following patentably distinct species: the presence or absence of an optional coating (see Claims 38, 40, 85, 87, 130, 132). If Applicant elects the presence of an optional coating, Applicant is further required to define the pharmaceutical additive with a particular species (a species definition such as methyl, not a genus such as alkyl). See Claims 39, 41, 86, 88, 131, 133. The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claims 1-37, 42-84, 89-129, 134-144 are generic to the above.

If Applicant elects Invention I above, Applicant is further required under 35 U.S.C. 121 to elect a single disclosed species for each of the following three election requirements:

First Election Requirement of Three

This application contains claims directed to the following patentably distinct species: the presence or absence of a primary release modifying agent (see Claims 1-4, 55, 100). If Applicant elects the presence of a primary release modifying agent, Applicant is further required to define the primary release modifying agent with a particular species (a species definition such as methyl, not a genus such as alkyl). See Claims 29-31, 79-81. The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claims 5-28, 32-54, 56-78, 82-99, 101-144 are generic to the above.

Second Election Requirement of Three

This application contains claims directed to the following patentably distinct species: the presence or absence of a secondary release modifying agent (see Claims 1-4, 55, 100). If Applicant elects the presence of a secondary release modifying agent, Applicant is further required to define the secondary release modifying agent with a

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particular species (a species definition such as methyl, not a genus such as alkyl). See Claims 32-34, 124-126. The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claims 5-31, 35-54, 56-99, 101-123, 127-144 are generic.

Third Election Requirement of Three

This application contains claims directed to the following patentably distinct species: the presence or absence of an auxiliary release modifying agent (see Claims 1-4, 55, 100). If Applicant elects the presence of an auxiliary release modifying agent, Applicant is further required to define the auxiliary release modifying agent with a particular species (a species definition such as methyl, not a genus such as alkyl). See Claims 35-36, 82-83, 127-128. The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is

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finally held to be allowable. Currently, Claims 5-34, 37-54, 56-81, 84-99, 101-126, 129-144 are generic to the above.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are

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added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Inventorship Notice

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul W. Dickinson whose telephone number is 571-270-3499. The examiner can normally be reached on Mon-Thur 7:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

PWD

Ardin H. Marschel 8/3/07
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER